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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,890	12/11/2003	Austin L. Gurney	P1861R1C1	4603

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,890	GURNEY ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Elections/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 47-51, and 54, drawn to a composition comprising a PRO256 polypeptide, classified in class 530, subclass 350.

II. Claims 1-2, drawn to a composition comprising a PRO256 agonist, classification dependent upon structure of agonist.

III. Claims 1-2, drawn to a composition comprising a PRO256 antagonist, classification dependent upon structure of antagonist.

IV. Claims 3-4, drawn to a method for identifying an agonist of a PRO256 polypeptide, classified in class 435, subclass 7.1.

V. Claims 5-7, drawn to a method for identifying a compound that inhibits activity of a PRO256 polypeptide comprising contacting cells with a test compound and determining induction of cellular response, classified in class 435, subclass 7.1.

VI. Claim 8, drawn to a method for identifying a compound that inhibits expression of a PRO256 polypeptide, classified in class 435, subclass 7.1.

VII. Claims 9-10, drawn to a compound that inhibits the expression of a PRO256 polypeptide, classified in class 435, subclass 7.1.

VIII. Claims 11-13, 19, and 52, drawn to an isolated antibody that binds PRO256, classified in class 530, subclass 387.1.

IX. Claim 14, drawn to a method for diagnosing a disease comprising determining the presence or absence of a mutation in a PRO256 polypeptide-encoding nucleic acid, classified in class 435, subclass 6.

X. Claim 15, drawn to a method of diagnosing a disorder in a mammal which comprises analyzing the level of expression of a gene encoding a PRO256 polypeptide, classified in class 435, subclass 6.

XI. Claim 16, drawn to a method of diagnosing a disorder in a mammal which comprises detecting the presence or absence of a PRO256 polypeptide, classified in class 435, subclass 7.1.

XII. Claims 17-18, drawn to a method of diagnosing a disorder in a mammal comprising contacting an anti-PRO256 polypeptide antibody with a test sample and detecting the formation of complex between the antibody and PRO256 polypeptide, classified in class 435, subclass 7.1.

XIII. Claims 20-24, 30, 32, and 34-35, drawn to a method of treating a disorder in a mammal comprising administering to the mammal a therapeutically effective amount of a PRO256 polypeptide, classified in class 424, subclass 184.1.

XIV. Claims 20-22, 30, 32, and 34-35, drawn to a method of treating a disorder in a mammal comprising administering to the mammal a therapeutically effective amount of a PRO256 agonist, classified in class 514, subclass 2.

XV. Claims 20-22, 31, 33, and 36-38, drawn to a method of treating a disorder in a mammal comprising administering to the mammal a therapeutically effective amount of a PRO256 antagonist, classified in class 514, subclass 2.

XVI. Claims 25-27, drawn to a method of treating a disorder in a mammal comprising administering to the mammal a nucleic acid molecule that encodes a PRO256 polypeptide, or agonist, or antagonist, classified in class 514, subclass 44.

XVII. Claims 28-29, drawn to a recombinant retroviral particle comprising a retroviral vector, classified in class 435, subclass 235.1.

XVIII. Claims 39-46 and 53, drawn to an isolated nucleic acid having at least 80% nucleic acid sequence identity to a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2, a vector, host cell, and method for producing a polypeptide, classified in class 536, subclass 23.5, for example.

The inventions are distinct, each from the other because of the following reasons:

a. Inventions I-III, VII-VIII, and XVII-XVIII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the DNA of group XVIII and the protein of Group I are patentably distinct inventions. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. The protein of Group II can be prepared by

processes which are materially different from recombinant DNA expression of Group XVIII, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group XVIII can be used other than to make the protein of Group I. The protein of Group I can be used in materially different methods other than to make the antibody of Group VIII, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group VIII can be used to obtain the DNA of Group XVIII, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. Finally, the agonists, antagonists, antisense, and viral particle of Groups II-III, VII, and XVII, respectively are structurally and functionally diverse from each other and the products of Groups I, VIII, and XVIII.

Furthermore, the distinct products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups I-III, VII-VIII, and XVII-XVIII.

b. Inventions IV-VI and IX-XVI are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). Groups IV-VI and IX-XVI are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention IV requires search and consideration of contacting cells and a test compound and determining the induction of a cellular response induced by the PRO256 polypeptide, which is not required by the other inventions. Invention V requires search and consideration of contacting a test compound with the PRO256 polypeptide and determining whether the activity of the polypeptide is inhibited, which is not required by the other inventions. Invention VI requires search and consideration of contacting cells that normally express the PRO256 polypeptide

with a test compound and determining whether expression of the polypeptide is inhibited, which is not required by the other inventions. Invention IX requires search and consideration of diagnosis of a disease by determining the presence or absence of a mutation in the PRO256 nucleic acid sequence, which is not required by the other inventions. Invention X requires search and consideration of diagnosis of a disease by analyzing the level of expression of a gene encoding a PRO256 polypeptide, which is not required by the other inventions. Invention XI requires search and consideration of diagnosis of a disease by detecting the presence or absence of a PRO256 polypeptide, which is not required by the other inventions. Invention XII requires search and consideration of diagnosis of a disease by contacting an anti-PRO256 antibody with a test sample and detecting the formation of a complex between the antibody and polypeptide, which is not required by the other inventions. Invention XIII requires search and consideration of administration of a PRO256 polypeptide, which is not required by the other inventions. Invention XIV requires search and consideration of administration of a PRO256 agonist, which is not required by the other inventions. Invention XV requires search and consideration of administration of a PRO256 antagonist, which is not required by the other inventions. Invention XVI requires search and consideration of administration of a PRO256 nucleic acid molecule, which is not required by the other inventions.

Furthermore, the distinct steps and products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups IV-VI and IX-XVI together.

c. Inventions I and IV-VI/XI/XIII are related as product and product of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product. See MPEP § 806.05(h). In the

instant case, the product claimed can be used in materially different processes, such as an antigen for the production of antibodies.
Additionally, searching the inventions of Groups I and IV-VI/XI/XIII together would impose a serious search burden. The inventions of I and IV-VI/XI/XIII have a separate status in the art as shown by their different classifications. Moreover, the search for a PRO256 polypeptide and the methods of use are not coextensive.

d. Inventions II and XIV are related as product and product of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product. See MPEP § 806.05(h). In the instant case, the product claimed can be used in materially different processes, such as *in vitro* cell culture and screening assays.
Additionally, searching the inventions of Groups II and XIV together would impose a serious search burden. The inventions of II and XIV have a separate status in the art as shown by their different classifications. Moreover, the search for a PRO256 agonist and the method of use are not coextensive.

e. Inventions III and XV are related as product and product of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product. See MPEP § 806.05(h). In the instant case, the product claimed can be used in materially different processes, such as *in vitro* cell culture and screening assays.
Additionally, searching the inventions of Groups III and XV together would impose a serious search burden. The inventions of III and XV have a separate

status in the art as shown by their different classifications. Moreover, the search for a PRO256 antagonist and the method of use are not coextensive.

f. Inventions VIII and XII are related as product and product of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product. See MPEP § 806.05(h). In the instant case, the product claimed can be used in materially different processes, such as therapeutic methods.

Additionally, searching the inventions of Groups VIII and XII together would impose a serious search burden. The inventions of VIII and XII have a separate status in the art as shown by their different classifications. Moreover, the search for a PRO256 antibody and the methods of use are not coextensive.

g. Inventions XVIII and IX-X/XVI are related as product and product of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product. See MPEP § 806.05(h). In the instant case, the product claimed can be used in materially different processes, such as DNA purification.

Additionally, searching the inventions of Groups XVIII and IX-X/XVI together would impose a serious search burden. The inventions of XVIII and IX-X/XVI have a separate status in the art as shown by their different classifications. Moreover, the search for a PRO256 DNA sequence and the methods of use are not coextensive.

h. Inventions I and IX, X, XII, XIV-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups I and IX, X, XII, and XIV-XVI are unrelated product and methods, wherein each is not required, one for another. For example, the isolated polypeptide of Invention I cannot be used together with the claimed methods of Inventions IX, X, XII, and XIV-XVI because these inventions do not recite the use or production of the polypeptide.

i. Inventions II and IV-VI, IX-XIII, XV-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups II and IV-VI, IX-XIII, XV-XVI are unrelated product and methods, wherein each is not required, one for another. For example, the agonist of Invention II cannot be used together with the claimed methods of Inventions IV-VI, IX-XIII, XV-XVI because these inventions do not recite the use or production of the agonist.

j. Inventions III and IV-VI, IX-XIV, XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups III and IV-VI, IX-XIV, XVI are unrelated product and methods, wherein each is not required, one for another. For example, the antagonist of Invention III cannot be used together with the claimed methods of Inventions IV-VI, IX-XIV, XVI because these inventions do not recite the use or production of the antagonist.

k. Inventions VII/XVII and IV-VI/IX-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP

§ 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups VII/XVII and IV-XVI are unrelated products and methods, wherein each is not required, one for another. For example, the antisense of Invention VII and viral particle of Invention XVII cannot be used together with the claimed methods of Inventions IV-XVI because these inventions do not recite the use or production of the antisense or viral particle.

l. Inventions VIII and IV-VI, IX-XI, XIII-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups VIII and IV-VI, IX-XI, XIII-XVI are unrelated product and methods, wherein each is not required, one for another. For example, the antisense of Invention VIII cannot be used together with the claimed methods of Inventions IV-VI, IX-XI, XIII-XVI because these inventions do not recite the use or production of the antisense.

m. Inventions XVIII and IV-VI, XI-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups XVIII and IV-VI, XI-XV are unrelated product and methods, wherein each is not required, one for another. For example, the DNA of Invention XVIII cannot be used together with the claimed methods of Inventions IV-VI, XI-XV because these inventions do not recite the use or production of the DNA.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification and

require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidenceor identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
29 September 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER